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BEDFORDSHIRE AND LUTON JOINT PRESCRIBING COMMITTEE

RHEUMATOLOGY SHARED CARE GUIDELINE for DMARDs

Shared Care Guideline

There are currently 6 Disease-modifying anti rheumatic drugs (DMARDs) in routine use by the Luton & Dunstable NHS Trust and Bedford Hospital Rheumatology Departments.

- **Methotrexate (oral or Subcutaneous injection)**
- **Sulfasalazine**
- **Leflunomide**
- **Azathioprine**
- **Mycophenolate**
- **Hydroxychloroquine**

Overarching Principles of Shared Care Guidelines

The introduction of these shared care guidelines for commonly used DMARDs facilitates the following aspects of patient care:

- **Patients can be seen and initiated on the most appropriate DMARD treatment regimen under the care of a Rheumatology Specialist team.**
- **The ongoing routine prescribing and blood test monitoring can be taken over by the patient's own GP (**at a mutually acceptable time as agreed between the GP and the Specialist - typically somewhere between 4 and 12 weeks after treatment started, depending on local GP practice preference).
- **GPs can contact the Rheumatology Specialist team directly for advice and support on an ongoing basis.**
- **Patients will continue to be reviewed by the Rheumatology Specialist team at scheduled out-patient appointments** (frequency will vary on an individual basis).

To initiate shared care:

- **All shared care arrangements rely upon** clear communication between the Specialist, GP and the individual patient and / or their carer.
- A member of the Specialist Rheumatology team should contact the patient's GP and discuss the concept of shared care at the point of initiation of DMARD therapy.
- If a GP is not able to participate fully with the shared care agreement, they are under no obligation to do so. In such an event, the total clinical responsibility for the patient for the diagnosed rheumatological condition will remain with the Specialist team.

Timing of Implementation of Shared care arrangements:
Due to practical reasons, there is currently a difference in practise between BCCG and LCCG as to when GPs will consider accepting prescribing and blood test monitoring responsibilities for DMARDs.

Local arrangements are:

- BCCG GPs – can consider accepting prescribing and blood test monitoring responsibility under shared care arrangement form week 4 onwards (NB: This may be prior to the patient being treated with a stable dose of the chosen DMARD).
- LCCG GPs – can consider accepting prescribing and blood test monitoring responsibility under shared care arrangement only when the patient has reached a stable maintenance dose. (NB: The time to reach a stable dose will vary depending on the DMARD chosen and individual patient factors.)

Blood Test Monitoring and Prescribing of DMARDs by GPs

As part of the shared care agreement, the GP as the prescribing clinician is responsible for the drug and the consequences of its use. The GP is therefore responsible for checking the blood test results PRIOR to the issue of a prescription of the specific DMARD. (This includes checking the blood test results even if the blood tests are requested by the Specialist at any point).

In situations when blood tests are ordered by the Specialist, the Specialist must ensure that a copy of the results are sent to the GP (either electronically or paper copy) in a timely manner to enable the GP to check the results prior to issuing a prescription.

Frequency of Blood Test Monitoring:
The British Rheumatology Society (BSR) have published a guideline:- Guidelines for disease-modifying anti-rheumatic drug (DMARD) therapy (2017) outlining the frequency of blood test monitoring. The BSR guidelines have in general, adopted a harmonised approach across the 6 DMARDs (where possible) in order to standardise the frequency of blood test monitoring. – Details of frequency are specified in Appendix 1.

NB: Patients are often prescribed more than one DMARD e.g. methotrexate and sulfasalazine. In general, monitoring of patients on more than one DMARD should be based on the DMARD which requires the most frequent monitoring.

Individual Responsibilities:

Hospital Specialist Team – At Initiation of therapy phase
• Contact the GP to request share care. • Inform GP that a copy of the Rheumatology Shared care guideline plus the relevant DMARD drug Prescribing information sheets (appendix 2) are downloadable from the BLMK Medicines website :- click here
• Confirm diagnosis and indication for drug treatment. • Assess the patient for any co-morbidities, including evaluation for respiratory disease and screening for occult viral infection e.g. varicella, when choosing the most appropriate DMARD therapy.

- Discuss potential benefits and side-effects of treatment with patient.
- Explain the blood test monitoring schedule and the importance of attending for regular blood tests to the patient.
- **Carry out baseline monitoring requirements.**
- Send a copy of the baseline test results to the GP for information (electronically or paper copy as appropriate).

- Provide patients with the relevant advice relating to the particular DMARD(s) being initiated e.g. contraception / varicella- zoster immunity / alcohol consumption / cytotoxic waste disposal.
- Advise patient to inform all healthcare professionals (e.g. GPs, A&E clinicians, community pharmacists) that they are taking DMARD therapy and that regular blood test monitoring is being undertaken.
- Advise patient to show a copy of the most recent clinic letter containing details of their current dose to the community pharmacist when presenting a prescription for DMARD therapy.

- Provide patient with any relevant patient information leaflet(s) for example:
  - National patient Safety agency (NPSA) patient information leaflet
  - Arthritis Research UK patient information leaflet
  - In-house developed patient information leaflet (if applicable)
- Provide patient with a patient-held monitoring & dosage record booklet (NPSA booklet or locally agreed equivalent booklet) and provide replacement booklets when required (if applicable.)

  NB: It has been agreed locally that blood tests do not need to be written in a patient-held monitoring booklet as blood test results can be accessed electronically by local GPs and the Specialist Rheumatology Team – If electronic access is not available, a decision as to whether to record the results in the patient booklet should be agreed between the Specialist team/ the GP and the patient on an individual basis.

- Check for possible drug interactions with existing medication, before initiating DMARD therapy. (Refer to individual SPCs / electronic BNF)
- Possible drug interactions should also be checked if prescribing any new medications or when stopping any concurrent medications at any point.
- Ensure that the hospital pharmacy computer software has the latest computer software updates relevant to the chosen DMARD, e.g. methotrexate alerts and prompts. (as per NPSA advice)

- **Initiate DMARD therapy** and prescribe until the shared care agreement begins – (this typically involves the Specialist providing the first 6 to 12 weeks (depending on BCCG LCCG commissioning position) supply of medication and then, the GP taking over both prescribing and blood test monitoring responsibilities).
- The initial prescription issued by the Specialist team should be for a 6 week supply of medication, and any subsequent prescriptions should be for a maximum of a 4 week supply at a time.
- Inform the GP of the prescription details i.e. dose and frequency. Avoiding phrases such as 'as directed'
- **Inform the GP if the patient is receiving any additional immunosuppressants or biologic drugs and the GP should ensure that this information is added to the patient's medical record.**
- Ensure that patient/ carer is trained in the administration and disposal of subcutaneous methotrexate (if applicable).

- Inform the patient to report any side-effects to the Specialist or GP
  (Clinicians should refer to the individual drug Summary of Characteristics (SPCs) and current electronic BNF for full details of side effects).

Blood Test Monitoring (See Summary of Blood Test monitoring schedule for the different DMARDs – Appendix 1)

If the GP agrees to share care from week 4 :

- Specialist should inform patient that they will require regular blood tests whilst taking DMARD therapy.
- **Specialist should provide an initial prescription for the first 6 weeks of therapy and issue the patient with 2 blood test forms (one for bloods at week 2 and one for bloods at week 4).**
- **Specialist to check the blood test results at week 2:**
- If satisfactory, Specialist to advise patient to have a repeat blood test at week 4 and explain that the GP will take over and that the GP should check the week 4 blood test results. If the week 4 results are satisfactory, the GP will then continue to prescribe and monitor blood tests in the long term as per the blood test schedule (appendix 1).
- Advise the patient that subsequent blood test monitoring forms should be obtained from their GP practice.

If the GP agrees to share care from when the patient is on a stable dose (typically from around 12 weeks):

- Specialist should inform patient that they will require regular blood tests whilst taking DMARD therapy.
- **Specialist should provide prescriptions for the DMARD medication until shared care with the GP is implemented.**
- **Specialist to issue blood test forms and to check the results for the duration of time until the GP agrees to share care.**
- **Once shared care is implemented,** the GP will then continue to prescribe and monitor blood tests in the long term as per the blood test schedule (appendix 1).
- Advise the patient that subsequent blood test monitoring forms should be obtained from their GP.

Shared care Responsibilities: Shared care can commence anytime from 4 weeks after DMARD therapy has been initiated by the Specialist Team. (exact timing will vary depending on individual GP practises).	
Specialist Rheumatology Team	**GP**
• Confirm that the GP will take over the prescribing **and** blood test monitoring from week 4 (or at other time as agreed with GP). • **Inform the GP of the frequency of blood tests that are required.** (See Summary of blood test monitoring schedule – Appendix 1) • Agree how the blood test results should be communicated between the Specialist team and the GP (i.e. electronically or paper copy), ensuring that blood test results can be accessed in a timely manner by both parties.	• Monitor the patient's overall health and well-being. • Update the patient's medical record to reflect the results of immunity screening and any vaccinations given prior to DMARD therapy. • Ensure that the patient's medical record is updated if the patients is also being prescribed an additional immunosuppressant or biologic agent by the Specialist Rheumatology team (as these are often solely prescribed by secondary care clinicians).
• Provide GP with advice on action required in the event of abnormal blood results / side effects when requested by the GP. **NB: If a clinically urgent blood test abnormality/ side effect occurs, the Specialist Rheumatology Team should provide advice within one working day.** NB: When advising the GP on a plan of action to be taken, ensure that the length of time that will elapse before the patient can be reviewed in the Specialist clinic is communicated with the GP.	• Agree to take over Prescribing for the specified DMARD at an agreed date (can be anytime from week 4 as per agreement). (NB: GPs should note that some patients, in particular those commenced on methotrexate may not yet be on a stable maintenance dose by week 4. In such cases, the Specialist team will provide the GP with written details of the dose escalation schedule.)
• Arrange to review the patient at Out-Patients as appropriate • Monitor the patient's response to therapy. Inform the GP of any changes made to the dosage / route of administration etc.	• At the agreed date (can be anytime from week 4), agree to take over blood test monitoring responsibility at the specified frequency as directed by the Specialist team. (See Summary of blood test monitoring schedule – Appendix 1)
• Monitor the patient for any side-effects to the specified DMARD therapy and inform the GP if any occur. Report any serious side-effects to the MHRA. (Refer to individual SPCs / electronic BNF for full details on side effects.)	• Check for possible drug interactions when prescribing any new medications or when stopping any concurrent medications. (Refer to individual SPCs/ electronic BNF) • Ensure that the GP practice (and dispensaries, if a dispensing practice) computer software has the latest software updates relevant to the chosen DMARD, e.g. methotrexate alerts & prompts. (as per NPSA advice)
Specialist Rheumatology Team	**GP**
• **Decide when to stop therapy and inform both the patient and the GP.**	• Monitor the patient for any side-effects to the specific DMARD therapy and refer back to the Specialist should any serious side-effect occur. Report side effects to MHRA if appropriate. (Refer to individual SPCs/ electronic BNF for full details on side effects.)
	Blood Tests : • Reiterate the importance of attending for regular blood test monitoring to the patient**.** • Advise patients to attend for a blood test approximately. one week before their next

	prescription is due to ensure that the results can be reviewed before the next prescription is requested for issue. • Ensure that blood test results are taken at the required frequency **AND check the results prior to the issue of a subsequent prescription.** (See Summary table of blood test monitoring frequency, Appendix 1 and individual drug prescribing information sheets)
	Blood Tests: Continued • Seek advice from the Specialist as to whether more frequent blood tests are required e.g. following any dose adjustments, in certain patient groups e.g. those with renal impairment , those on more than one DMARD. • Record blood test results in the GP medical record. Send a copy of the blood tests to the Specialist for information unless previously agreed electronic access is available. **NB** The Specialist will not routinely review the blood test results - this process is to allow the Specialist to review blood test results in the event when a GP contacts them for advice and also when reviewing the patient in outpatient clinic. • Refer any patient who fails to attend for regular blood test monitoring back to the Specialist team. • Contact the Specialist for advice with regards any action that should be taken in the event of abnormal blood results / side effects. **NB: If a clinically urgent abnormality, the Specialist Rheumatology Team should provide advice within one working day.**
	Subsequent Prescriptions: • Provide subsequent prescriptions and ensure that 'repeat prescriptions requests' for all DMARDs (with the exception of Hydroxychloroquine) are retained separately for **"prescriber review prior to authorisation"** as they are regarded as high risk drugs which require a review of blood test results by the GP prior to issuing of a prescription. • Provide a **maximum of 4 weeks supply at a time**. This is applicable to all DMARDs. • When prescribing methotrexate tablets, **only prescribe the 2.5mg strength tablets**. (This has been agreed locally as a way to reduce confusion and to reduce the risk of dispensing errors.) • Prescribe any concomitant medication as specified by the Specialist (if applicable) e.g. for patients on methotrexate, prescribe folic acid as directed by the Specialist team.
Specialist Rheumatology Team	**GP**
	• Re-iterate any relevant advice e.g. information with regards contraception / varicella zoster immunity / alcohol / waste disposal - see the individual drug Prescribing drug information sheets (Appendix 2). • Discuss drug therapy and management plan of any pregnant patients/any patients considering pregnancy or anyone wishing to breastfeed with the Specialist Rheumatology team.
	Infections • Initiate prompt anti-infection treatment when indicated on the basis that the patient may be immunosuppressed to some degree.

	• During a serious infection, DMARD therapy (except Hydroxychloroquine) should be temporarily discontinued until the patient has recovered from the infection. NB Serious infection = warrants admission to hospital or requires parenteral anti-microbial therapy. • For patients who are non--immune and exposed to measles or chickenpox, contact the Specialist Rheumatology team **asap** for consideration of appropriate immunoglobulin therapy. • If patient contracts chickenpox or shingles, contact Specialist and treat with acyclovir.

Patient Responsibilities	**Community Pharmacist Responsibilities**
• Discuss potential benefits and side-effects of treatment with the Specialist and GP and share any concerns they have in relation to their treatment.	• Be familiar with side effects and blood test monitoring requirements for individual DMARDs. (Refer to Individual SpCs www.medicines.org.uk/emc / electronic BNF and Individual Prescribing drug information sheets.- Appendix 2)
• Report any side-effects to the Specialist or GP. • **Report immediately**, any breathlessness, dry cough, whites of eyes becoming yellow, severe itching of skin, rash, dark urine, infections (including fever, chills or severe sore throats), new unexplained bleeding or bruising, mouth ulcers, vomiting and diarrhoea (particularly if occurs at the start of treatment, or if it is severe, at any stage in treatment).	• Check with patient that a recent blood test has been taken and the results checked by the GP / Specialist team **before** dispensing DMARD medication. • Contact the prescribing clinician (GP / Specialist) if in any doubt about the dosage prescribed or if any concerns relating to blood test monitoring and blood test results
• Inform all healthcare professionals (e.g. GP's, A&E clinicians, community pharmacists) that they are taking DMARD therapy and that regular blood test monitoring is being undertaken.	• Provide adequate counselling on the use of the specified DMARD(s). • Advise patients to take folic acid as specified by the prescriber ensuring that folic acid is NOT taken on the same day as methotrexate (if applicable).
• Show a copy of the most recent clinic letter containing current prescription details e.g. dose and frequency to the community pharmacist when presenting a prescription for DMARD therapy.	• Be familiar with the NPSA guidance on methotrexate http://www.nrls.npsa.nhs.uk/resources/?entryid45=59800
Patient Responsibilities	**Community Pharmacist Responsibilities**
• Participate in the monitoring of therapy (including having blood tests carried out at agreed intervals) and assessment of outcomes. • Ensure that a blood test is taken in advance of running out of medication to allow time for the results to come back.	
• Patients who are non-immune to measles and or varicella-zoster should notify GP and / or Specialist of any inadvertent exposure to a person with measles / chicken pox so that	

passive immunity can be given with the appropriate immunoglobulin therapy.	
• To acknowledge advice given e.g. regarding contraception, alcohol, varicella, cytotoxic waste disposal.	
• To use adequate contraception and report any suspected pregnancy to the GP / Specialist Team.	
• To inform GP / Specialist of all medicines (including OTC preparations) currently being taken.	
• To follow cytotoxic waste disposal procedure as advised by Specialist team (if applicable)	

BACK-UP ADVICE AND SUPPORT

- **GP queries should be directed to the Rheumatology consultants.**
- **Patient queries should be directed to the Rheumatology Specialist Nurses**

All urgent requests should be answered within one working day.

CONTACT DETAILS

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Updated April 2022 – blood test schedules changed back to BSR schedules
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Appendix 1

Summary of Blood Monitoring Schedule for DMARDs

(Reference: The blood test schedule is based on current clinical practise and the BSR Guidelines - Guidelines for disease-modifying anti-rheumatic drug (DMARD) therapy (2017). https://academic.oup.com/rheumatology/article/56/6/865/3053478

Blood Tests required each time : FBC, creatinine/calculated GFR, ALT and/or AST and albumin

DMARD (Single drug)	Blood Test Monitoring Schedule	Other Monitoring

○ **Methotrexate (MTX)** ○ **Azathioprine (AZA)** ○ **Leflunomide (LEF)**	○ every 2 weeks until on a stable dose for 6 weeks, **then** monthly blood tests for 3 months **then** every 12 weeks* longer-term ***More frequent monitoring is appropriate for patients at a higher risk of toxicity**.	○ Leflunomide – Monitor BP and weight at each monitoring visit. ○ Azathioprine – Assess baseline Thiopurine methyltransferase (TPMT) status.
○ **Sulfasalazine (SSZ)**	○ every 2 weeks until on a stable dose for 6 weeks, **then** monthly blood tests for 3 months **then** every 12 weeks.* ***More frequent monitoring is appropriate for patients at a higher risk of toxicity.** ○ Routine blood test monitoring is only required for the first 12 months of therapy, after which time no routine monitoring is needed.	
○ **Mycophenolate (MMF)**	○ every 2 weeks until on a stable dose for 6 weeks, **then** monthly blood tests for 3 months **then** every 12 weeks* longer-term ***More frequent monitoring is appropriate for patients at a higher risk of toxicity.**	
○ **Hydroxychloroquine (HCQ)**	○ No routine laboratory monitoring required.	○ Baseline formal ophthalmic examination (ideally including objective retinal assessment e.g. using optical coherence tomography (OCT), within one year of starting therapy. ○ Annual eye assessment (ideally including OCT) if continued for > 5 yrs.
Combination therapy		
Leflunomide and Methotrexate (LEF/MTX)	○ every 2 weeks until on a stable dose for 6 weeks, **then monthly blood tests longer- term*** ***More frequent monitoring is appropriate for patients at a higher risk of toxicity.** ○ Patients who have been stable for 12 months can be reviewed by the Specialist team and considered for reduced frequency of monitoring on an individual basis.	
Other combinations	○ Monitoring of patients on more than one DMARD should be based on the DMARD which requires the most frequent monitoring.	

Please note :

For all DMARDs :

- **If the dose is increased at any time, blood test monitoring should increase to every 2 weeks until on a stable dose for 6 weeks then monthly for 3 months, then revert back to previous schedule (as specified above).**
- ***More frequent monitoring is appropriate for patients at a higher risk of toxicity.**

Appendix 2

Prescribing Information sheets for GPs:

Contents: Click relevant item below

- Methotrexate (oral or Subcutaneous injection) – (For patients under the care of the **Luton & Dunstable hospital only)**
- Methotrexate (oral or Subcutaneous injection**)** – (For patients under the care of **Bedford Hospital only**)

- **Sulfasalazine**
- **Leflunomide**
- **Azathioprine**
- **Mycophenolate**
- **Hydroxychloroquine** (updated June 2021)